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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,809	05/05/2005	Richard Hercek	271135US0PCT	4302
22850	7590	04/18/2008		
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER SACKEY, EBENEZER O	
			ART UNIT	PAPER NUMBER
			1624	
			NOTIFICATION DATE	DELIVERY MODE
			04/18/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/533,809	Applicant(s) HERCEK ET AL.	
	Examiner EBENEZER SACKEY	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05/05/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Claims 1-7 are pending.

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Information Disclosure Statement

Receipt of the Information Disclosure Statement filed on 05/05/05/ is acknowledged and has been entered into the file. A signed copy of the 1449 is attached herewith.

Claim Rejections - 35 U.S.C. § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-7 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Wiedemann et al., (U.S. Patent number 4,503,067).

Applicants claim a method for preparing Carvedilol, which comprises reacting to 4-(oxirane-2-ylmethoxy)-9Hcarbazole with a salt of 2-(2-methoxyphenoxy)-ethylamine in a specific ratio of the starting materials in the presence of a base in an alcohol solvent.

Determination of the scope and content of the prior art (MPEP §2141.01)

Wiedemann et al., teach a process for preparing Carvedilol which comprises reacting 4-(2, 3-epoxypropoxy)-carbazole with 2-(2-methoxyphenoxy)-ethylamine in the presence of ethylene glycol dimethyl ether in an alcohol solvent. See the entire reference especially column 5, Example 2 and column 6, Example 3.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the current process and that of Wiedemann et al., resides in the base employed in the process (claims 1 and 3). The instant process requires the use of an alkali metal or alkaline earth metal carbonate in C₂₋₅ alcohols, whereas Wiedemann teaches the use of ethylene glycol dimethyl ether. However, the use of various solvents in organic chemistry to effect the rate of reaction and reactivity is well-known. Note the broad use of organic solvents in column 4, line 25. Thus, the current process is considered non-inventive. It is noted that claims 1 and 7 are drawn to the use of specific ratios of reactants which is not taught in the reference, however, the use of specific ratios are well within the purview of the skilled artisan. Note the process limitations of claim 5 and 6 that is wherein reaction mixtures are cooled, filtered and recrystallized in Example 2, 3 to obtain the crude product. Also note the use of ethyl acetate (claim 7) in Example 4, line 51, and C₃ alcohol i.e., isopropanol (claim 2) in Example 4f. Note the wide range of temperatures taught for this process which ranges from ambient temperature to 147°C.

Hence, the claimed ratios, concentrations and temperatures are an obvious modification available to one of ordinary skill in the art. These are merely optimization of variables, which are not patentable absent unexpected result due to these variables, and which difference may be a difference in kind, and not merely in degree from that of the prior

art. *In re Aller*, 105 USPQ 233, (1955). Also see *In re Boesch*, 205 USPQ, 215, (1980).

Finding of prima facie obviousness---rational and motivation (MPEP §2142-2143)

Thus, at the time of filing this application, one of ordinary skill in the art would be motivated to substitute one solvent for another, in the instance, alkali or alkaline earth metal carbonate as claimed herein for ethylene glycol dimethyl ether since the substitution of the solvents does not affect the outcome of the compound prepared by the process because the same reactants are being used by the current invention and the prior art. Hence, instantly claimed process would therefore have been suggested to one of ordinary skill in the art absent a showing of unexpected results and/or properties.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. Sackey whose telephone number is (571) 272-0704. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached on (571) 272-0661. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

EOS

**/James O. Wilson/
Supervisory Patent Examiner, Art Unit 1624**